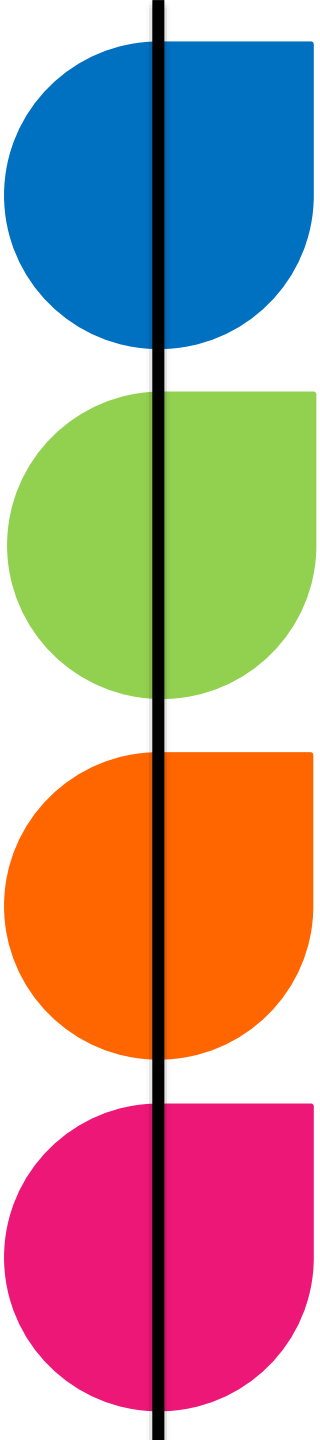


reachcentrum

ERM

JSC

Preparing and submitting an application for *in situ* substances

ECHA Biocides Stakeholders' Day
September 1, 2016

TEAM

MANAGEMENT

Support for **individual or grouped companies** applying or for a family or individual biocidal products authorisation – EU or national

TECHNICAL EXPERTISE

Scientific experts delivering regulatory and testing strategy services, providing Chemical, Toxicological and Exotoxicological expertise

- Approval of active substances
- Authorisation of biocidal products

PRODUCT SUSTAINABILITY SERVICES

Strong, globally connected team focused on providing both local and global knowledge of market drivers and regulatory landscape

This unique combination ERM-ReachCentrum-JSC provides a wealth of knowledge and experience covering a wide range of product types and regulatory procedures to support clients through the value chain

CONTENT

WHAT ARE *IN SITU* SUBSTANCES?

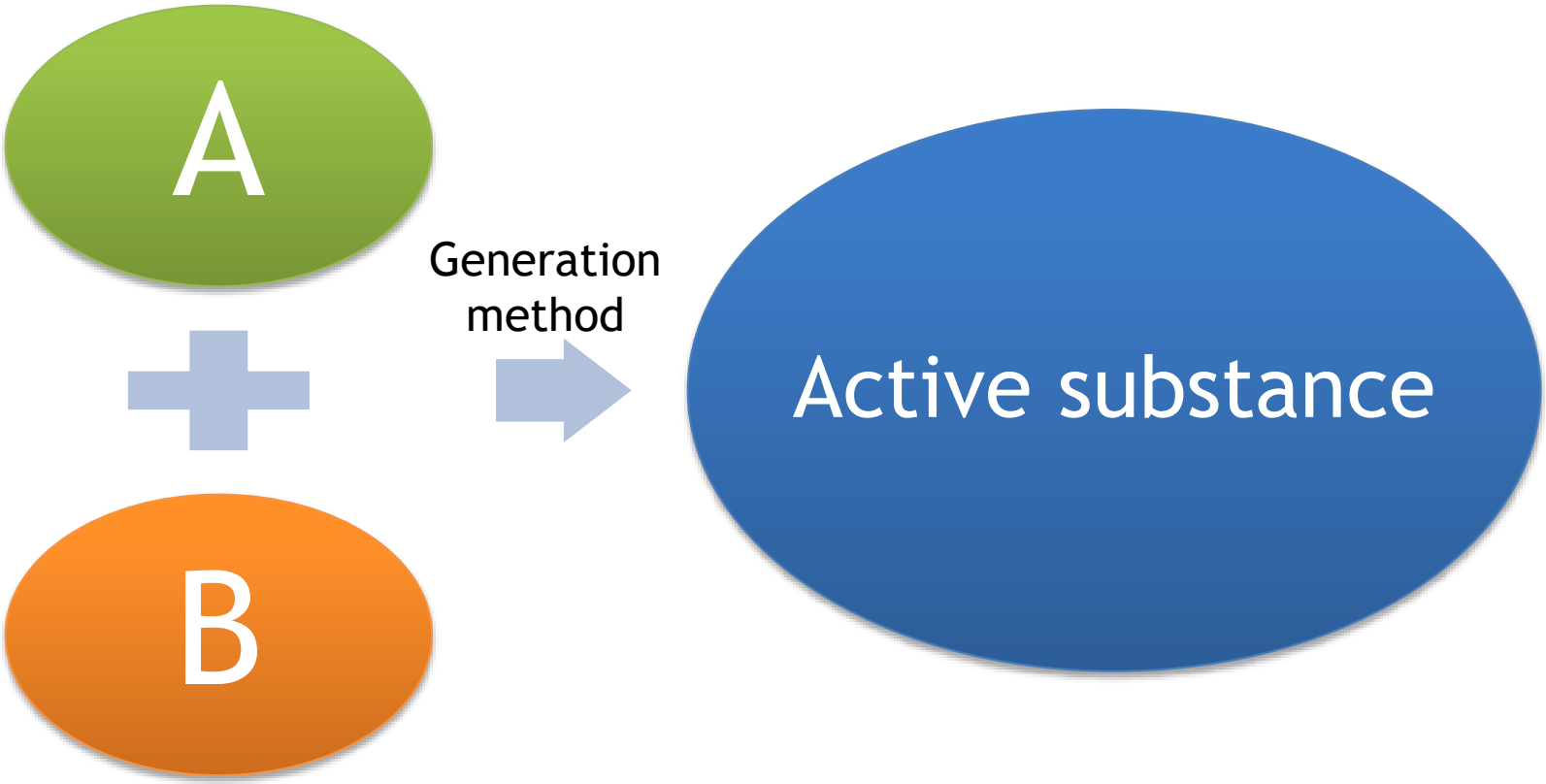
OBLIGATIONS

TECHNICAL REQUIREMENTS

DOSSIER SUBMISSION

IN SITU SUBSTANCES

- Substances that are generated from one or more precursors at the place of use



ARTICLE 3((1)(A)) OF BPR 528/2012

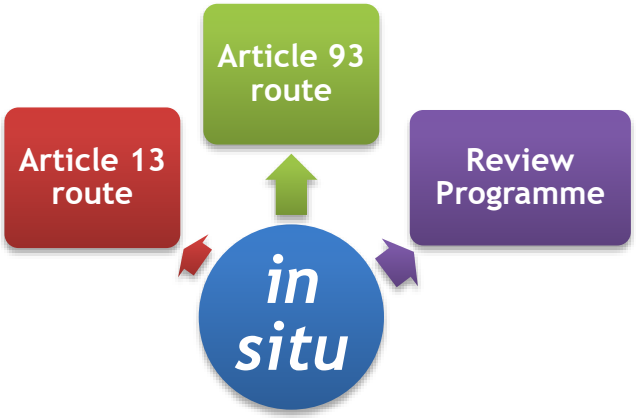
The definition of biocidal product confirms that:

- The supply of a precursor with the intention to generate an *in situ* biocide
- Biocides generated from ambient precursors that are not supplied

➡ Falls under the *in situ* generated substance

IN SITU SUBSTANCE CONT.

- Agreement between MSCAs and the European Commission
- For all substances generated *in situ*, the active substance must be defined by reference to the precursor(s) supported in the dossier and to the substance generated

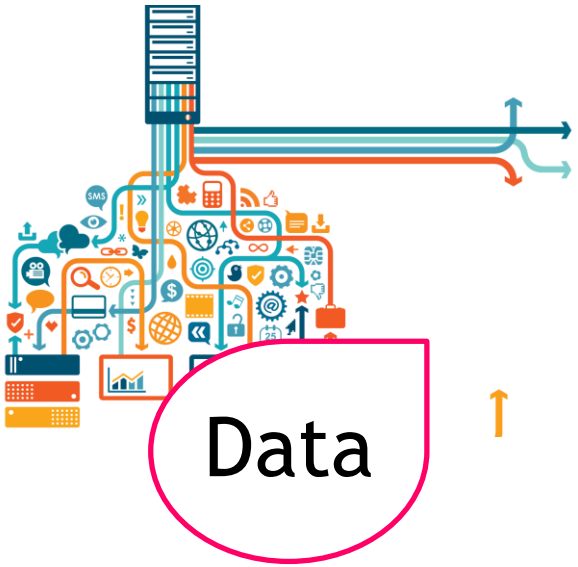


DOSSIER PREPARATION

For *in situ* generated active substance, the dossier will need to cover data on both the *in situ* substance and the precursor(s), as well as other relevant substances in terms of generating the active

DATA ANALYSIS

Where the active substance is generated *in situ* then 5-batch analysis data on the precursors and the active substance itself is required



DESCRIPTION OF THE METHOD OF APPLICATION

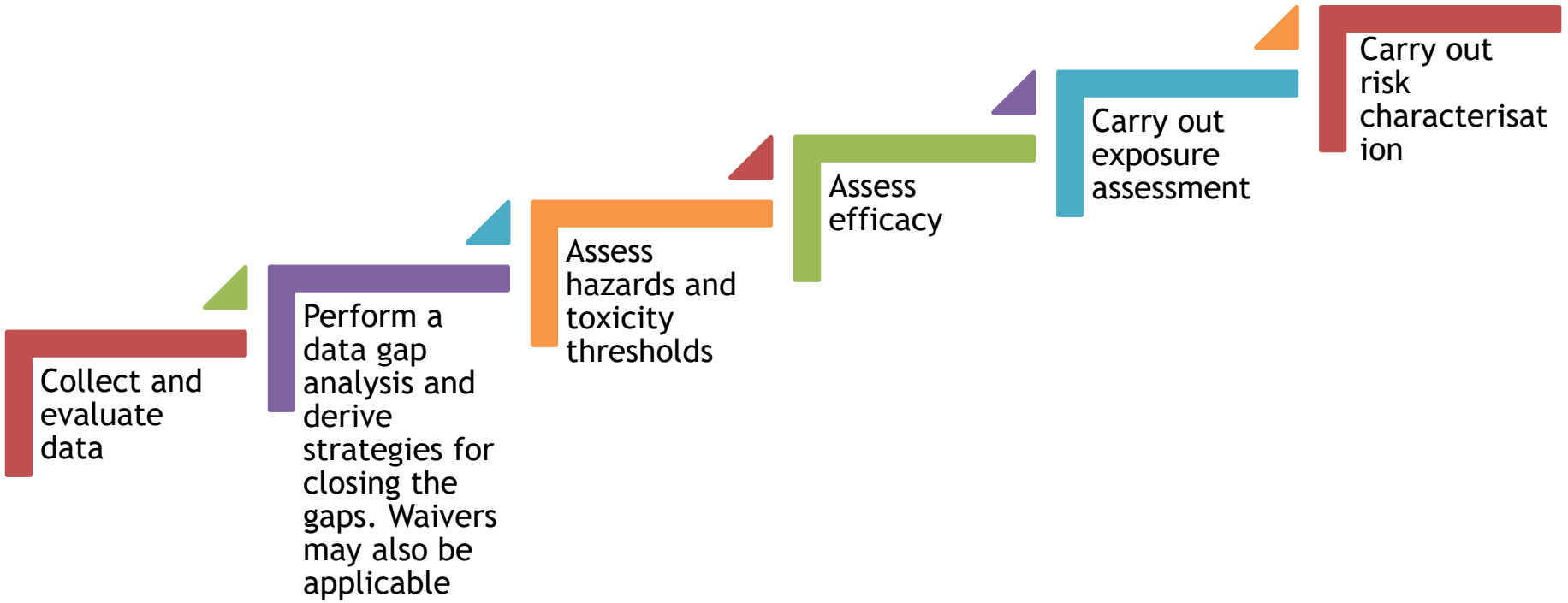
If an apparatus is used to produce the active substance *in situ* and to dose it directly, information should be provided on safety measures concerning over and under dosing

Method

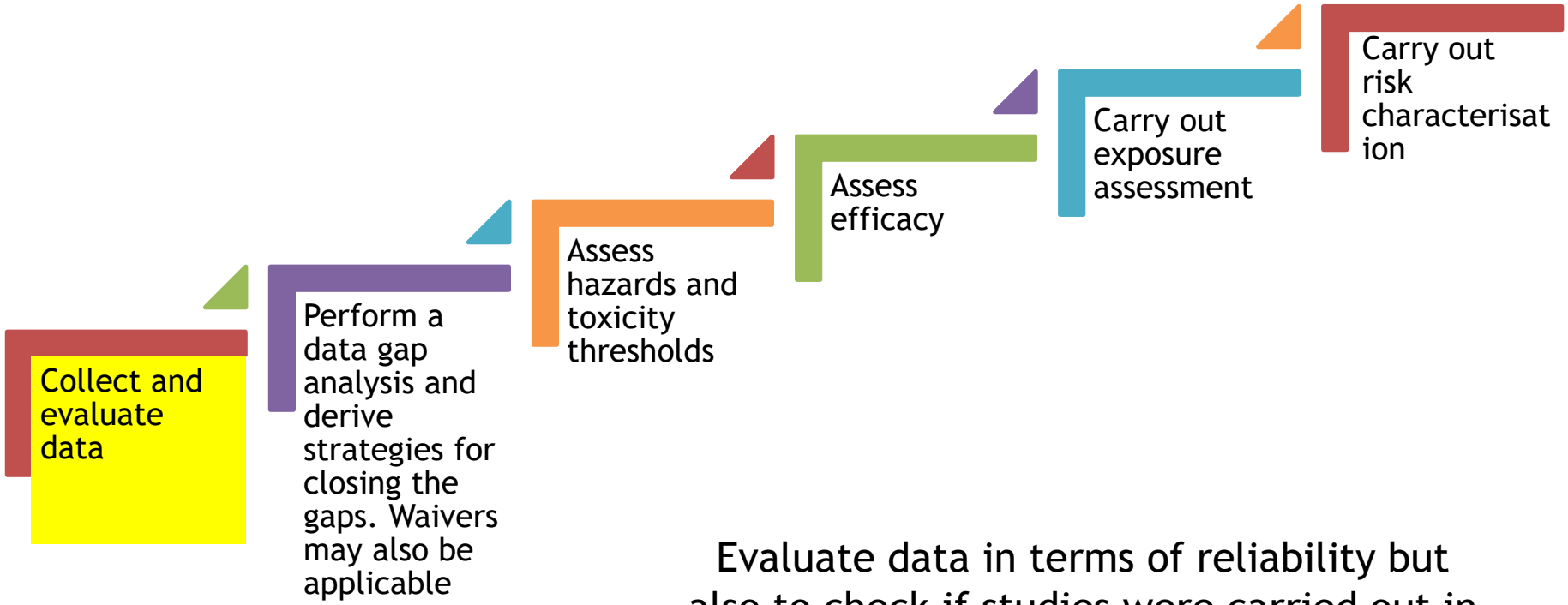
RISK ASSESSMENT

For *in situ* generated active substance, the risk assessment includes also the possible risks from the precursor(s)

TECHNICAL STEPS IN APPROVAL/AUTHORISATIONS PROCESSES

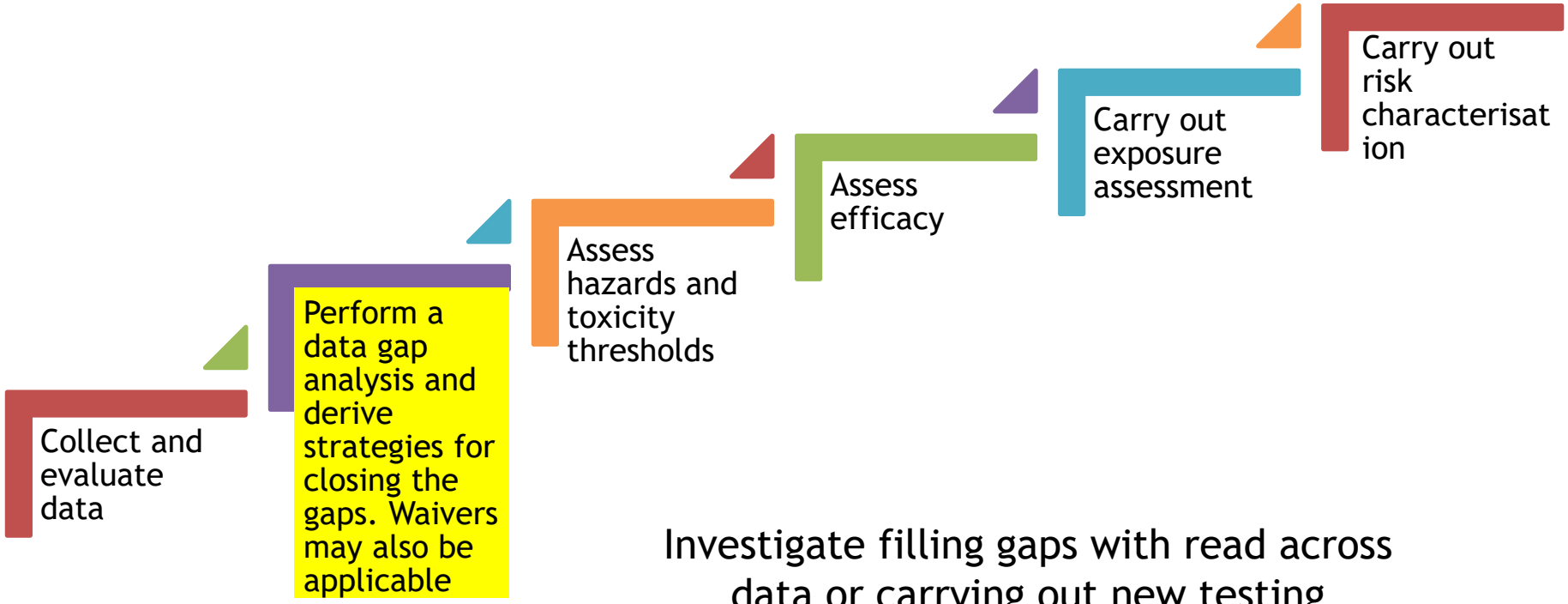


COLLECT DATA



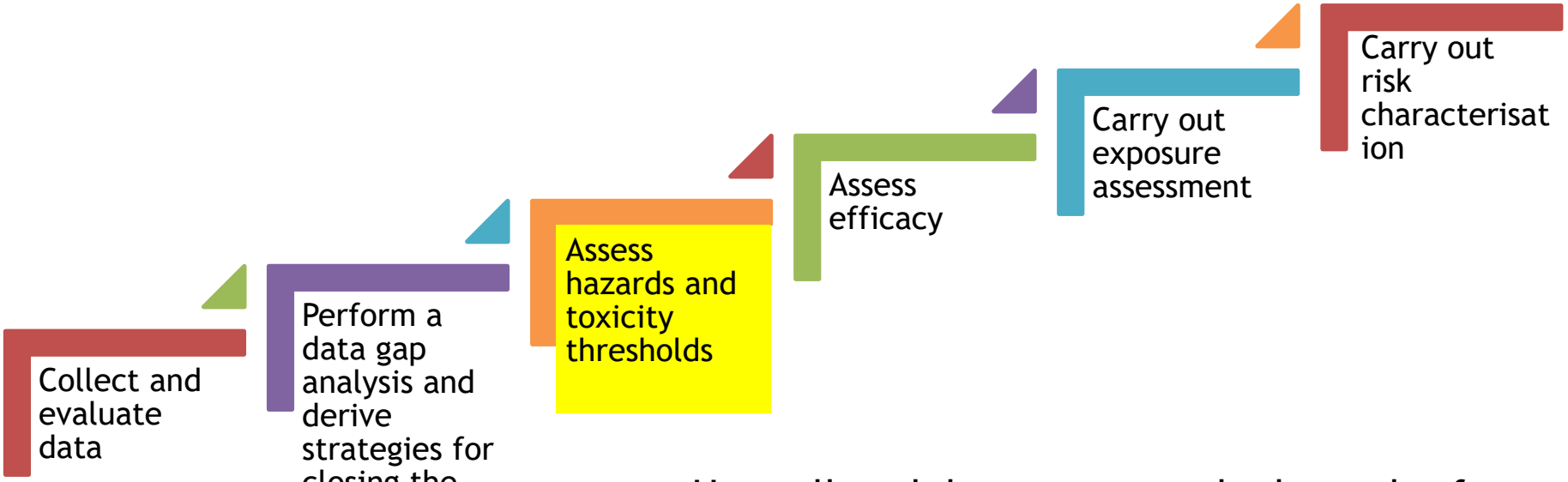
Evaluate data in terms of reliability but also to check if studies were carried out in accordance with approved protocols i.e. OECD

DATA GAP ANALYSIS



Investigate filling gaps with read across data or carrying out new testing

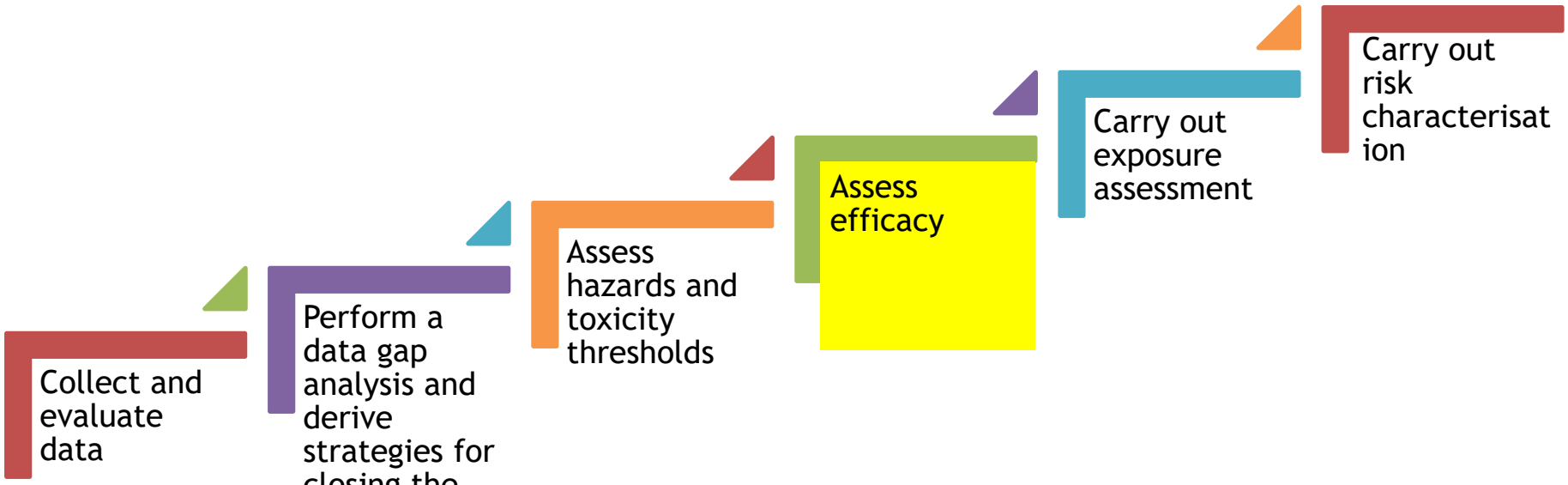
DERIVING HAZARDS AND THRESHOLDS



Use collated data to assess the hazards of the substance i.e. acute toxicity, irritation, reproductive toxicity

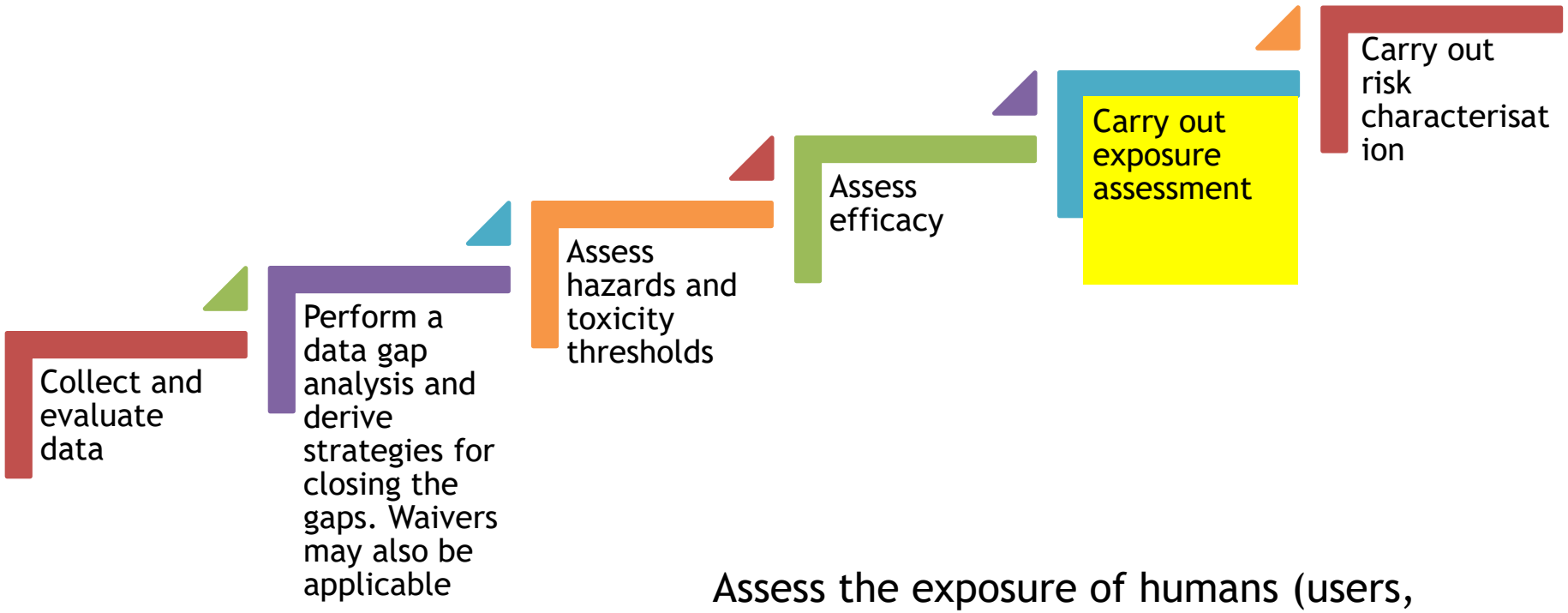
Derive toxicity threshold using the toxicity data i.e. the level that is not dangerous to humans or environment

ASSESS EFFICACY



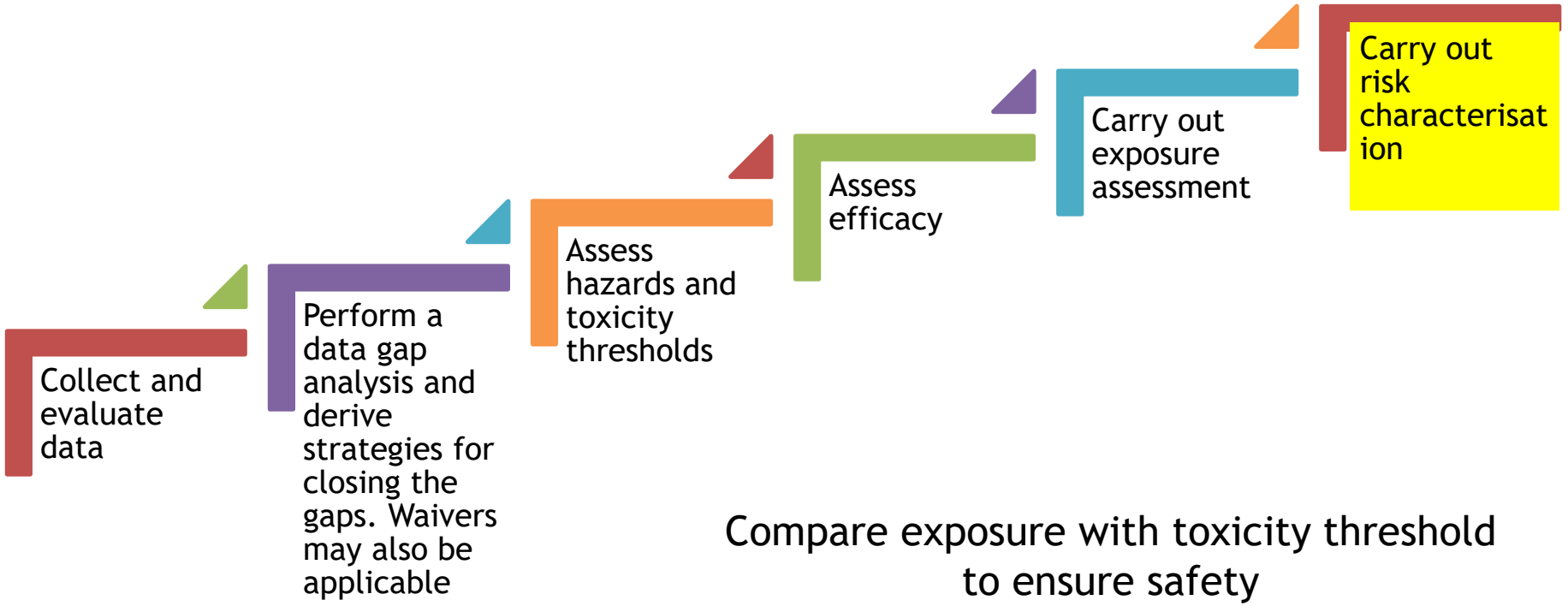
Assess effectiveness against target organisms

ASSESS EXPOSURE



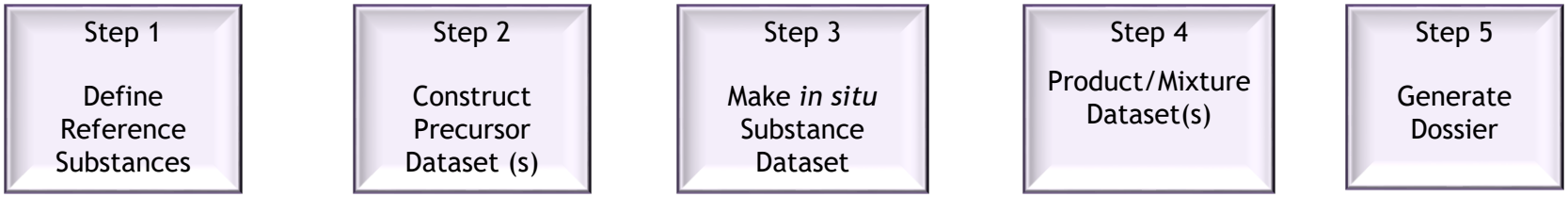
Assess the exposure of humans (users, bystanders, general public) using EU standard models (ECETOC TRA (Chesar), BEAT, ConsExpo)

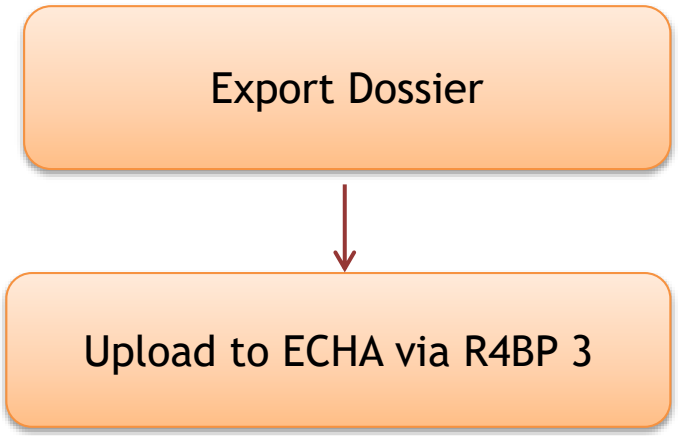
CHARACTERISE THE RISK



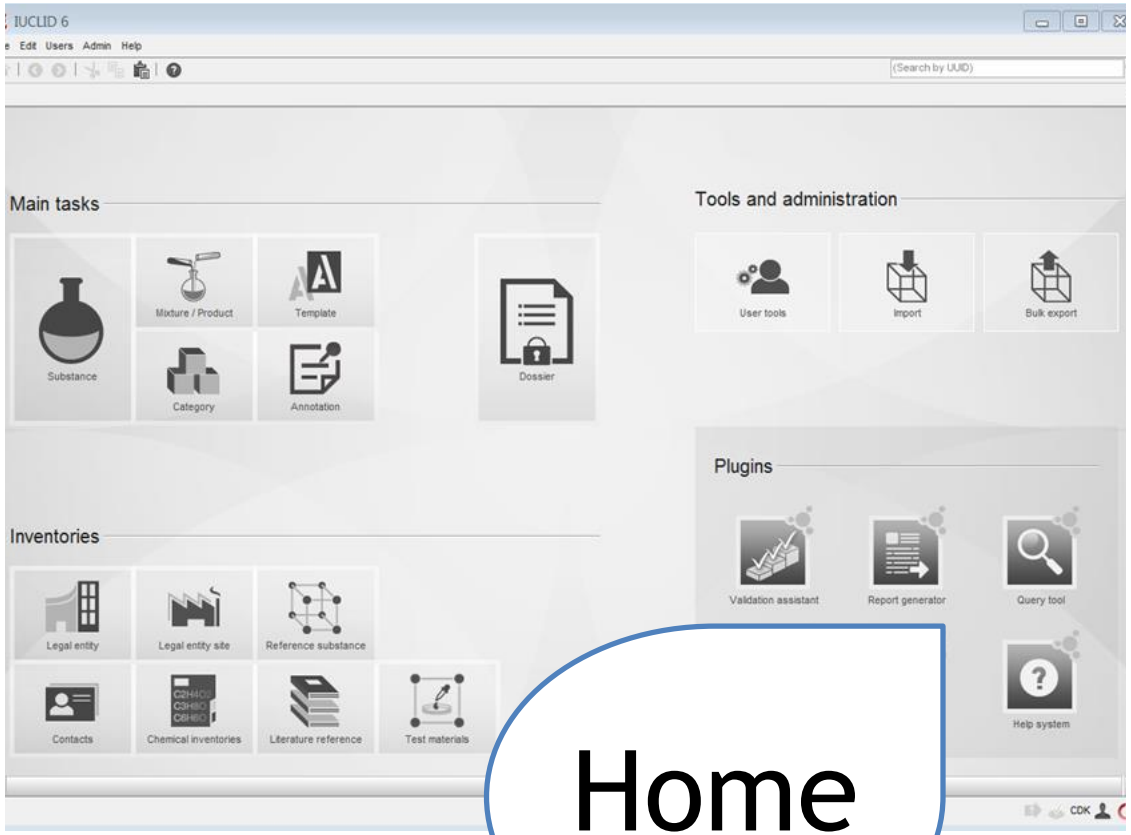
Compare exposure with toxicity threshold to ensure safety

TECHNICAL DOSSIER

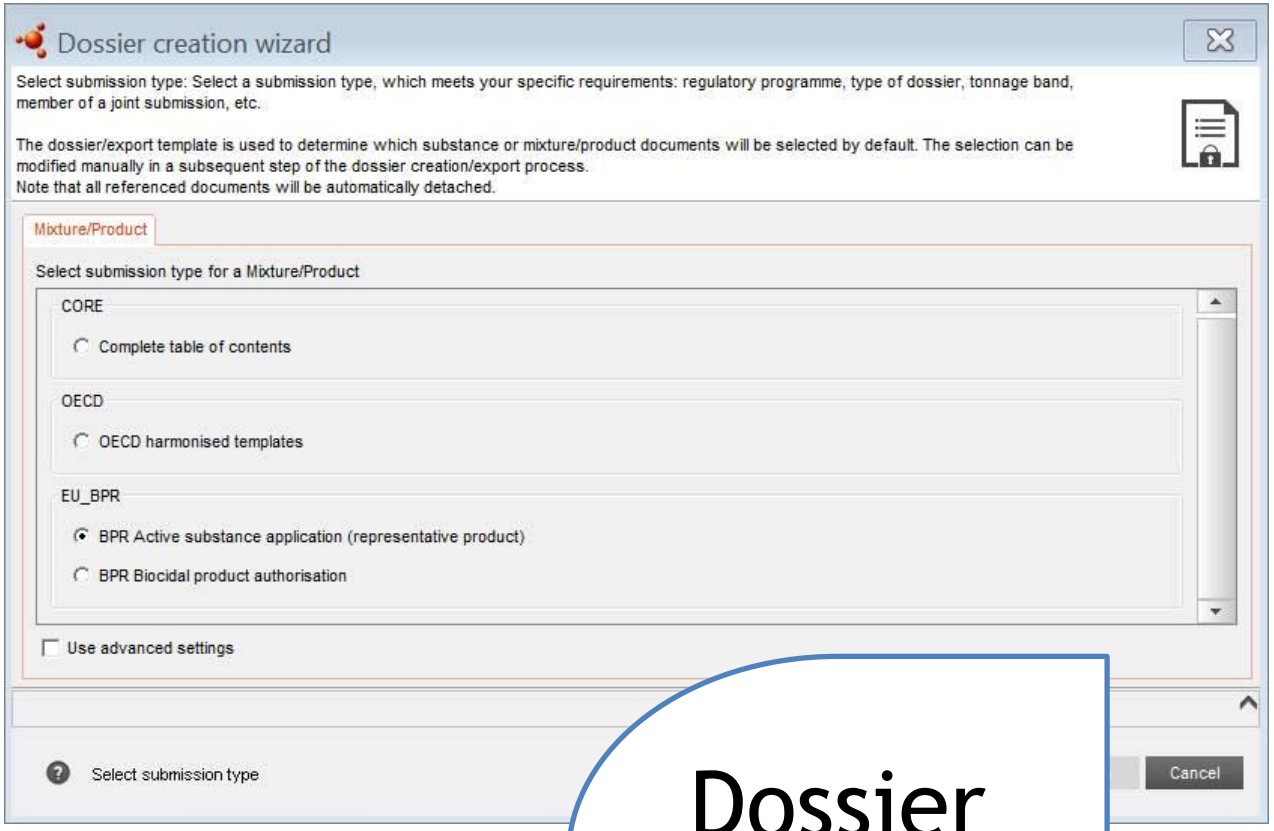




IUCLID 6

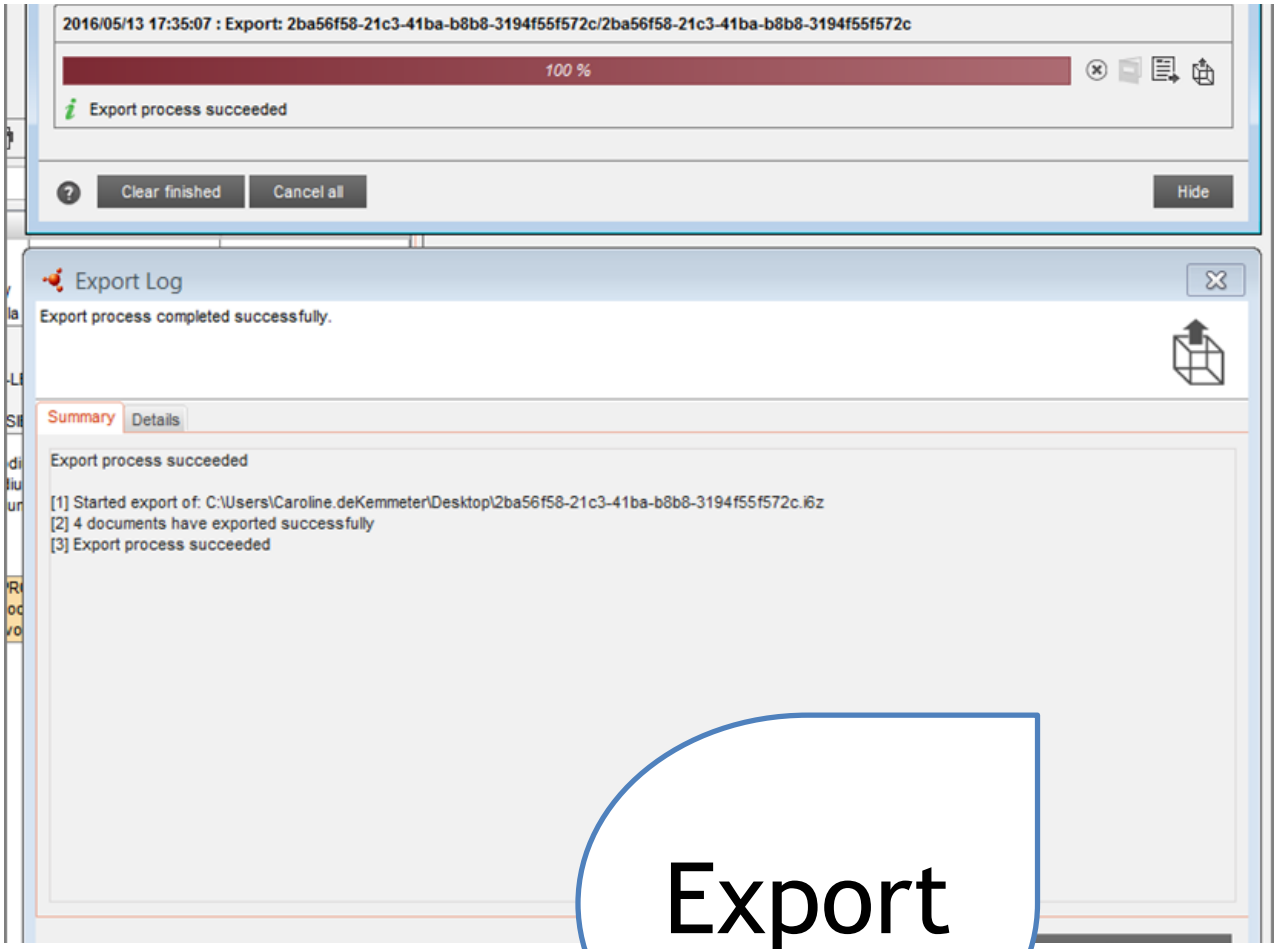

IUCLID 6
Edit Users Admin Help
(Search by UUID)
Main tasks
Substance
Mixture / Product
Template
Category
Annotation
Dossier
Tools and administration
User tools
Import
Bulk export
Plugins
Validation assistant
Report generator
Query tool
Help system
Inventories
Legal entity
Legal entity site
Reference substance
Contacts
Chemical inventories
Literature reference
Test materials
CDK
Home

IUCLID 6



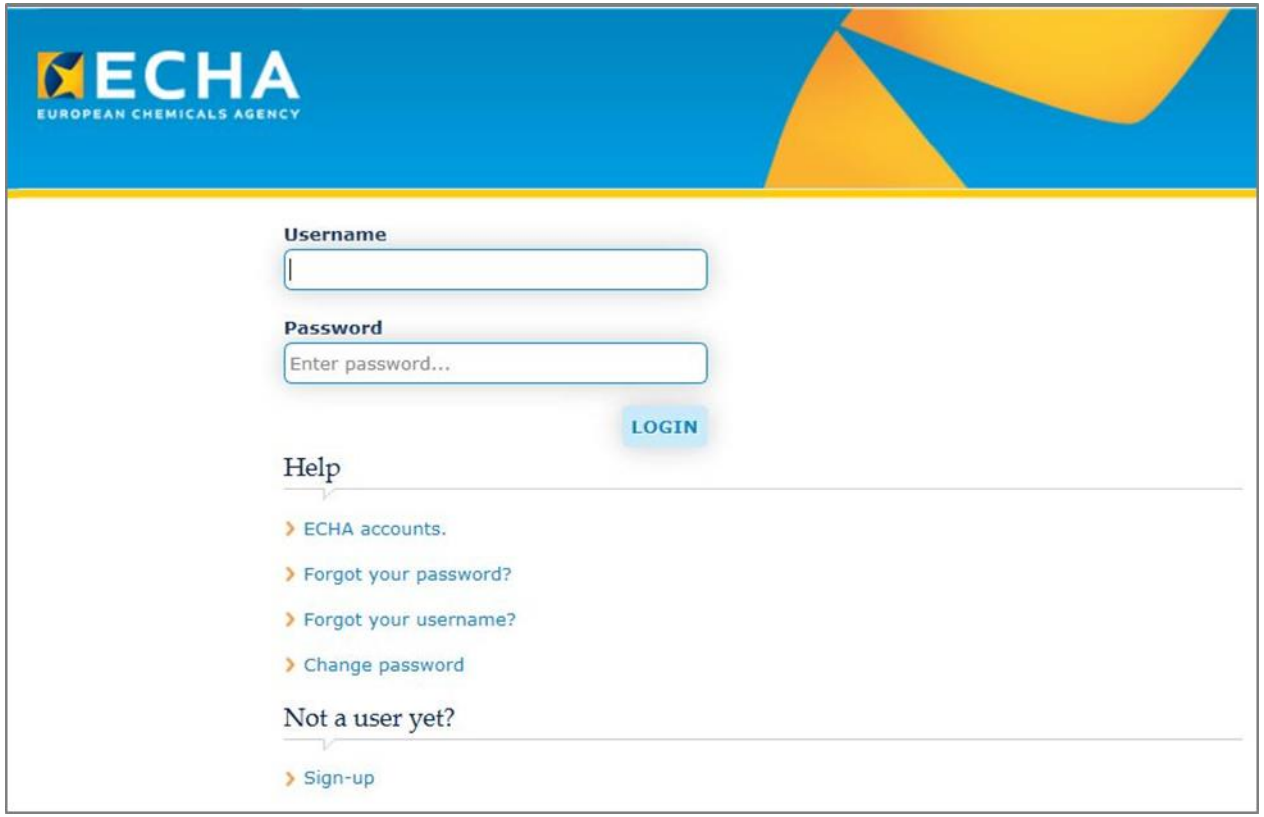
Dossier creation

IUCLID 6

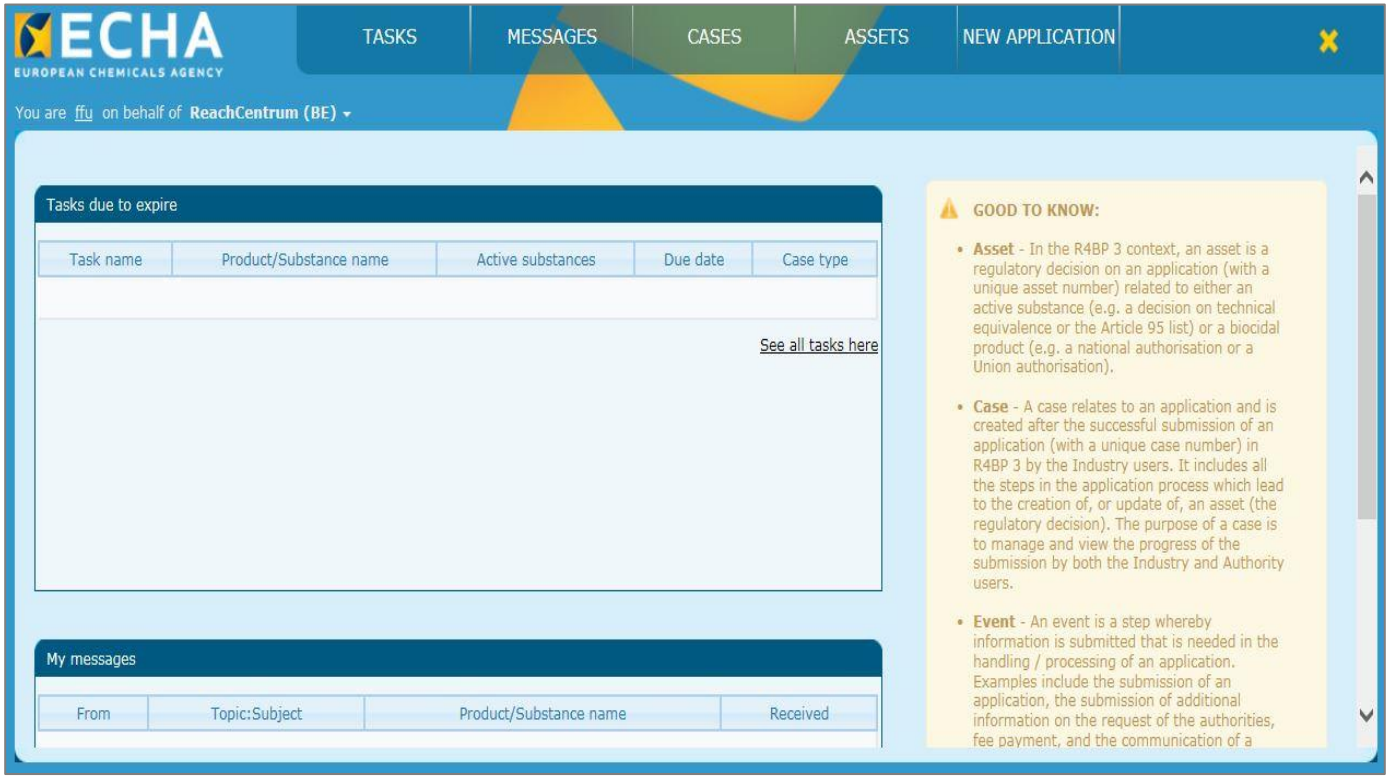


Export

R4BP3


ECHA
EUROPEAN CHEMICALS AGENCY
Username
Password
Enter password...
LOGIN
Help
ECHA accounts.
Forgot your password?
Forgot your username?
Change password
Not a user yet?
Sign-up

R4BP3


ECHA
EUROPEAN CHEMICALS AGENCY
TASKS
MESSAGES
CASES
ASSETS
NEW APPLICATION
You are ffu on behalf of ReachCentrum (BE)
Tasks due to expire
Task name
Product/Substance name
Active substances
Due date
Case type
See all tasks here
My messages
From
Topic:Subject
Product/Substance name
Received
GOOD TO KNOW:
Asset - In the R4BP 3 context, an asset is a regulatory decision on an application (with a unique asset number) related to either an active substance (e.g. a decision on technical equivalence or the Article 95 list) or a biocidal product (e.g. a national authorisation or a Union authorisation).
Case - A case relates to an application and is created after the successful submission of an application (with a unique case number) in R4BP 3 by the Industry users. It includes all the steps in the application process which lead to the creation of, or update of, an asset (the regulatory decision). The purpose of a case is to manage and view the progress of the submission by both the Industry and Authority users.
Event - An event is a step whereby information is submitted that is needed in the handling / processing of an application. Examples include the submission of an application, the submission of additional information on the request of the authorities, fee payment, and the communication of a

Thank you for your attention

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